

FEB 07 2002

## 3.0 510(k) Summary

SPONSOR: Synthes (USA)  
1690 Russell Road  
Paoli, PA 19301  
(610) 647-9700  
Contact: Thomas M. Maguire

DEVICE NAME: Fast Set Putty

CLASSIFICATION: Class II, 21 CFR 882.5300: Methyl Methacrylate for Cranioplasty.

PREDICATE DEVICE: Documentation was provided which demonstrated Fast Set Putty to be substantially equivalent to other previously cleared devices.

DEVICE DESCRIPTION: Fast Set Putty is a putty-like calcium phosphate bone cement characterized by a rapid *in situ* setting time. The Fast Set Putty components are supplied sterile in two separate containers. The putty is intraoperatively prepared by manually mixing the components within a cup using a spatula. Once complete, the putty can be shaped and contoured by hand.

INTENDED USE: Fast Set Putty is indicated for repairing or filling craniofacial defects and craniotomy cuts with a surface area no larger than  $25\text{cm}^2$ . Fast Set Putty is also indicated for the restoration or augmentation of bony contours of the craniofacial skeleton, including the fronto-orbital, malar and mental areas.

MATERIAL: Calcium Phosphate

Y1



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**FEB 07 2002**

Mr. Thomas M. Maguire  
Project Leader, Regulatory Affairs  
Synthes (USA)  
1690 Russell Road  
Paoli, Pennsylvania 19301

Re: K012589

Trade/Device Name: CRS Fast Set Putty  
Regulation Number: 21 CFR 882.5300  
Regulation Name: methyl methacrylate for cranioplasty  
Regulatory Class: Class II  
Product Code: GXP  
Dated: December 6, 2001  
Received: December 10, 2001

Dear Mr. Maguire:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

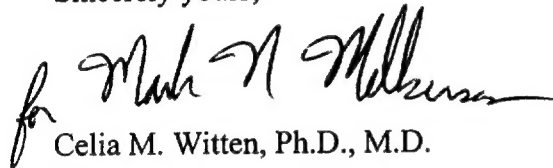
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Thomas M. Maguire

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Celia M. Witten".

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



## 2.0 Indications for Use Statement

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510(k) Number (if known): K012589

Device Name: Synthes (USA) Fast Set Putty

### Indications/Contraindications:

Fast Set Putty is indicated for repairing or filling craniofacial defects and craniotomy cuts with a surface area no larger than  $25\text{cm}^2$ . Fast Set Putty is also indicated for the restoration or augmentation of bony contours of the craniofacial skeleton, including the fronto-orbital, malar and mental areas.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

*for Mark A. Miller*  
(Division Sign-Off)  
Division of General Restorative  
and Neurological Devices

510(k) Number K012589